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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,770	11/21/2003	Stewart J. Lebrun	MGENE.016A	3300

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EXAMINER	
YANG, NELSON C	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/09/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/09/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No.	Applicant(s)	
	10/719,770	LEBRUN, STEWART J.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-16 and 21-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16 21-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/6/05, 2/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 13-16 in the reply filed on January 19, 2007 is acknowledged.

2. Claims 1-12, 18-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 19, 2007.

Response to Amendment

3. Applicant's cancellation of claims 1-12, 17-20 is acknowledged and has been entered.

4. Applicant's addition of claims 21-36 is acknowledged and has been entered.

5. Applicant's amendment of claim 13 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 13-16, 21-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, applicants have not shown any data that would suggest that the presence of antibodies to L35

protein, eukaryotic translation elongation factor 1 α-2, NADH dehydrogenase 3, 24-kDa subunit of complex I, mitotic kinesin like protein 1, thromboxane synthase, or uncoupling protein homolog is indicative of autoimmune disease, more specifically, of rheumatoid arthritis.

8. While applicants have discussed a possible role of L35 protein in rheumatoid arthritis, it is not clear that the mere presence of antibodies to L35 protein is indicative of autoimmune disease or if they are in fact a marker for autoimmune disease. As applicant themselves have disclosed, elevated levels of antibodies to L35 protein are expressed in patients suffering from rheumatoid arthritis; this would suggest that antibodies to L35 protein are also found in normal, healthy patients, although at a lower level. Applicant has not shown any additional data or disclosed any art that would clearly demonstrate that the presence of any of the above markers has been definitively linked to autoimmune disease, in particular rheumatoid arthritis.

9. Nor would one of ordinary skill in the art at the time of the invention have expected to know that these markers would be capable of use in screening for autoimmune disease, more specifically rheumatoid arthritis, as the prior art at the time of the invention does not provide evidence that the presence of antibodies to these markers would be indicative of autoimmune disease. Nor would one of ordinary skill in the art at the time of the invention have predicted that the presence of antibodies to these proteins would lead to a diagnosis of autoimmune disease. Even with L35 protein, applicants themselves disclose a link between elevated levels of antibodies to the protein and rheumatoid arthritis, and do not discuss a link between the mere presence of antibodies to L35 protein and rheumatoid arthritis. Therefore, one of ordinary skill in the art would not have reasonably expected the presence of antibodies to L35 protein to be

indicative of RA. Furthermore, one of ordinary skill in the art would have no reason to associate any of the other markers with autoimmune disease or rheumatoid arthritis.

10. Furthermore, the claims recite an immobilized polypeptide or fragment thereof homologous to at least a portion of at least a portion of at least one protein selected from L35 protein, eukaryotic translation elongation factor 1 α-2, NADH dehydrogenase 3, 24-kDa subunit of complex I, mitotic kinesin like protein 1, thromboxane synthase, and uncoupling protein homolog. This limitation would encompass fragments as small as one amino acid, which would clearly not be sufficient for use in determining the presence of autoimmune disease. Nor has applicant indicated how large a portion of the proteins would be necessary for the homolog to function in order to correctly bind to antibodies that are found only autoimmune disease. Therefore, one of ordinary skill in the art would not have had an reasonable expectation of success in determining the presence of autoimmune disease, more specifically rheumatoid arthritis using the method as recited.

11. According to Strongin (Strongin, Sensitivity, specificity, and predictive value of diagnostic tests: definitions and clinical applications, 1993, Laboratory Diagnosis of Viral Infections, p. 211-219), a number of characteristics need to be considered in the development of any suitable diagnostic assay. These characteristics include the sensitivity of the assay, the true-positive test rate, the false-negative test rate, the specificity, the true-negative test rate, the false positive test rate, the predictive value, the prevalence, the efficiency or percentage of all results that are true, and the accuracy of the recited diagnostic assay. However, none of these characteristics appear to have been considered.

12. Additional considerations must also be examined to enable the clinician to practice the invention, including assessment of when the maximum sensitivity, maximum specificity, and maximum efficiency are desired, how is the maximum sensitivity or specificity achieved, and how is the predictive value maximized. An essential understanding of these factors is required to enable the skilled artisan to accurately use and interpret any given diagnostic test. Specifically, the specification fails to provide data that statistically links the presence of the above markers to autoimmune disease, rendering it unclear how statistically significant are the results of this method in determining autoimmune disease or rheumatoid arthritis.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nelson Yang
Patent Examiner
Art Unit 1641

LONG V. LE 3/02/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600